UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ELI DAYAN, individually on behalf of himself and others similarly situated, Plaintiff, - against - SWISS-AMERICAN PRODUCTS, INC., Defendant.	:	1:15-cv-06895-DLI-VMS

MEMORANDUM OF LAW IN SUPPORT
OF DEFENDANT'S MOTION TO DISMISS

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Defendant Elta MD, Inc., formerly known as Swiss-American Products, Inc. ("Swiss-American") respectfully submits this Memorandum of Law in support of its motion to dismiss the Complaint (ECF No. 1), pursuant to Fed. R. Civ. P. 12(b)(6), and for a stay of discovery pending the Court's disposition of the motion.

PRELIMINARY STATEMENT

This putative class action asserts a single "false labeling" claim under the guise of 10 causes of action, one of which seeks relief pursuant to the consumer protection laws of 42 states. It purports to be brought on behalf of a nationwide class of purchasers of a sunscreen product sold by Swiss-American. As a matter of law, Plaintiff's Complaint should be dismissed, in its entirety and with prejudice, because each of the 10 causes of action is pre-empted by the federal law governing the labeling of sunscreen.

Swiss-American manufactures and sells a variety of over-the-counter ("OTC") drugs, including an award-winning sunscreen called EltaMD® UV Aero Broad-Spectrum SPF 45 ("UV Aero"). Available without a prescription but only through authorized doctors' offices, UV Aero is a water-resistant, broad-spectrum sunscreen, designed to protect against both ultraviolet aging and ultraviolet burning rays. The "SPF 45" on UV Aero's label refers to a "sun protection factor" of 45, a numerical designation of the sunscreen's strength derived from a highly technical testing protocol mandated by the United States Food and Drug Administration (the "FDA"). Under the federal Food, Drug and Cosmetic Act (the "FDCA"), the FDA has exclusive authority to regulate the testing and resulting statements of SPF values on sunscreen labels, and to enforce the FDCA's provisions.

Inspired by a review of UV Aero in Consumer Reports magazine, this quintessential lawyer-driven class action claims that UV Aero's SPF value is lower than the SPF 45 on the label. According to the Complaint, Plaintiff himself was "unaware" of the review when he

purchased the product in the summer of 2015, and found, for reasons he does not specify, that it "did not work." After Plaintiff "became aware" of the review, he, or more likely his class action attorney, hired a company to conduct an "independent" test of UV Aero's SPF value, which, allegedly, found a lower SPF value for UV Aero than the SPF 45 stated on the label. Plaintiff's class action attorney then sent Swiss-American a draft of the complaint and a letter threatening suit, masqueraded as a request for "information to refute" Plaintiff's claim.[1] Despite Swiss-American's good faith response providing such information, this vexatious action followed.

Plaintiff's lengthy complaint, consisting of 134 numbered paragraphs and asserting 10 causes of action, distills to a single material allegation: the SPF value of UV Aero is allegedly lower than the stated value of 45, thereby rendering UV Aero "misbranded" under the FDCA. Plaintiff does not allege that any other aspect of UV Aero's label is false or misleading.

All of Plaintiff's claims are pre-empted by the FDCA. Under federal law, the FDA has exclusive authority to enforce the FDCA's sunscreen labeling requirements and, pursuant to that authority, has issued detailed regulations mandating the use of a highly technical testing protocol to determine SPF values. Shockingly, but perhaps not surprisingly, Plaintiff filed this action despite knowing that no less than four FDA-compliant tests have independently validated the SPF 45 value of UV Aero. Although Plaintiff deliberately omitted any reference to those tests in his Complaint, the Court properly can, and should, consider them on this motion to dismiss since Plaintiff had notice and copies of the test reports prior to filing his Complaint. Because all of Plaintiff's claims are pre-empted, the Complaint should be dismissed, with prejudice.

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[1] One may safely presume that, in addition to attempting to obtain information from Swiss-American outside the normal discovery process, Plaintiff's attorney sent his letter to enable Plaintiff to allege, as he now does, that Swiss-American was placed "on notice" of a purported breach of warranty regarding the SPF 45 value on UV Aero's label and given "an opportunity to cure its breach," but "refused" to do so. (Compl. ¶ 100.)

STATEMENT OF FACTS

Swiss-American manufactures and sells the sunscreen UV Aero, which advertises an SPF value of 45 on its label. Plaintiff's Complaint acknowledges that the FDCA governs the labeling of SPF values on sunscreens and that an FDA regulation, 21 C.F.R. § 201.327(a)(1), "requires that every sunscreen must contain an SPF value derived from FDA-approved testing." (Compl. ¶¶ 3-4, 8-9, attached as Ex. 1 to the Declaration of Joseph J. Saltarelli, executed January 22, 2016 ("Saltarelli Dec.")).

Plaintiff alleges that although UV Aero's label displays an SPF value of 45, in May 2015, Consumer Reports tested it and "determined that the SPF levels [for UV Aero] were below their claimed values and less than SPF 30." (Id. ¶¶ 12-13.) Allegedly unaware of Consumer Reports' review, Plaintiff purchased UV Aero in the summer of 2015 and "was induced to pay a premium price for the product" based upon the label's statement that it had an SPF value of 45. (Id. ¶ 15.) "To his dismay," Plaintiff found that the product "did not work." (Id.) Plaintiff does not specify why or how he determined that UV Aero "did not work."

Plaintiff "[t]hereafter became aware of the Consumer Reports testing and results." (Id. ¶ 16.) He does not explain how he became aware of the review, but apparently intent on vindicating the rights of a nationwide class of UV Aero purchasers, Plaintiff went to the trouble of retaining an "independent laboratory" to test the product. According to Plaintiff, his test "was compliant with the FDA testing protocol for SPF validation" and revealed an SPF value of 18, less than one-half the SPF 45 value set forth on UV Aero's label. (Id. ¶¶ 16-17 & Compl. Ex. A (attaching copy of the test report by Suncare Research Laboratories, LLC ("Suncare Labs")).)[2]

[2] Plaintiff does not attach to his Complaint the "test" that allegedly yielded an SPF value of 18. Instead, he attaches a prior test that claims to assign UV Aero an SPF value of 22, but which on its face does not comply with FDA requirements for SPF testing. Those regulations require a test panel of no less than 10 members, while Plaintiff's test used just six members.

Plaintiff claims that after Consumer Reports published its review, Swiss-American "published a document entitled 'FAQs about EltaMD UV Aero' in which [Swiss-American] spuriously attempted to discredit Consumer Reports' testing protocol." (Id. ¶ 14.) The FAQs document, which Plaintiff relied upon to prepare his Complaint, was and remains publicly available at http://eltamd.com/product/uv-aero-broad-spectrum-spf-45/ (accessible under the link "SPF Validation"). (See Saltarelli Dec., Ex. 2.)

The FAQs document states that Swiss-American contacted Consumer Reports about its testing of UV Aero, and explains in detail why the Consumer Reports testing was not compliant with the protocol mandated by the FDA.

Plaintiff's Complaint does not allege that Consumer Reports tested UV Aero's SPF value in accordance with the FDA's mandated testing protocol. Nor does he dispute the reasons for Consumer Reports' non-compliance with the FDA testing protocol publicly articulated by Swiss-American. In fact, Plaintiff knew when he filed the Complaint that Consumer Reports had not tested UV Aero in accordance with the FDA's mandated testing protocol because its deviations from the protocol were described in the Swiss-American FAQs document Plaintiff relied upon in preparing his Complaint, and because Swiss-American's counsel advised Plaintiff's counsel that Consumer Report had, in fact, informed Swiss-American that when rating UV Aero it was "not performing compliance testing or making determinations [that the] product is in accordance with FDA regulations." (Id., Ex. 5.) Plaintiff omitted all of this information from his Complaint.

Attached to the FAQs document is a copy of a November 21, 2011 test report conducted for Swiss-American by AMA Laboratories, Inc. ("AMA Labs"), an independent, FDA-registered laboratory, which validated the SPF 45 value for UV Aero. (Id., Ex. 2.) The FAQs document

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Plaintiff's purportedly "compliant" test is instead referenced by the third party consultant who apparently arranged the test on behalf of Plaintiff's counsel. (See Compl., Ex. A, at page 5.)

explains that, after Consumer Reports published its review, Swiss-American submitted UV Aero to AMA Labs, and another independent laboratory, Bioscreen Testing Services, Inc. ("Bioscreen"), for additional FDA-compliant testing – both labs confirmed the SPF 45 value on UV Aero. AMA Labs and Bioscreen are both FDA-registered testing laboratories.[3] An earlier document entitled "Validation of EltaMD® UV Aero SPF Ratings," published on Swiss-American's website on May 15, 2015, shortly after release of the Consumer Reports review, also included a copy of AMA Labs' November 21, 2011 test report. (Saltarelli Dec., Ex. 3, available at http://eltamd.com/development/wp-content/uploads/2013/08/Validation-of-EltaMD-Sunscreen-SPF-Ratings_Letter-Web1.pdf.)

On October 19, 2015, after Swiss-American had twice published AMA Labs' November 2011 report on its website, Plaintiff's attorney sent a draft complaint to Swiss-American. In a cover letter, the attorney made clear he had reviewed the November 2011 test report validating the SPF 45 value. In requesting that Swiss-American's legal department contact him, he wrote: "And if you have any other information to refute [Plaintiff's claim of misbranding] *besides the test that your company conducted in 2011*, please provide same to us." (Saltarelli Dec., Ex. 4 (emphasis added).)

On October 30, 2015, counsel for Swiss-American replied to Plaintiff's counsel. (Id., Ex. 5.) Attached to the response were copies of three FDA-compliant test reports validating mean SPF values for UV Aero in excess of 45. The November 2011 AMA Labs test report, publicly

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[3] See http://www.accessdata.fda.gov/scripts/cder/drls/getDRLS.cfm. AMA Labs' FDA registration number is 2434339; Bioscreen's registration numbers (two FDA-registered testing facilities) are 2027219 and 3005630502. The Court may take judicial notice of AMA Labs' and Bioscreen's FDA registrations as they are a matter of public record. E.g., Vale v. Great Neck Water Pollution Control Dist., 80 F. Supp. 3d 426, 433 (E.D.N.Y. 2015) (court "may take judicial notice of documents in the public record, which includes records and reports of administrative bodies").

accessible on Swiss-American's website, was not included with Swiss-American's counsel's response because Plaintiff's counsel already had a copy of it. (Id., Exs. 4, 5.)

Although he omitted any reference to the FDA-compliant test reports validating Swiss-American's SPF testing and labeling process, Plaintiff attaches to his Complaint an "Independent Test Report," which appears to be a five-page summary by "i3 Engineering Services" of a "Final Report" issued by Suncare Labs, dated September 28, 2015 (the "Suncare Report"). Based on a search of the publicly-accessible FDA website, Suncare Labs does not appear to be an FDA-registered testing facility. (See *supra*, n. 3). The summary refers to two "separate panels" Suncare Labs allegedly used to test UV Aero: the first, which achieved an SPF value of 22.17, and a second, which achieved an SPF value of 19.71. (Compl. Ex. A, at page 5.) The text of the Suncare Report itself appears to describe only the results of the first "panel" and the SPF value of 22.17. Page 4 of the Suncare Report states that the test "panel" consisted of six subjects, four fewer than the 10 subjects required by the FDA. (See 21 C.F.R. § 201.327(i)(3).)

Betraying Plaintiff's cognizance of Suncare's material deviation from the FDA-mandated testing protocol – Swiss-American's counsel had brought the defect to the attention of Plaintiff's counsel prior to his filing suit– the Suncare Report contains two spreadsheet-style pages both numbered "5", the first indicating a test panel of 6 subjects and a mean SPF value of 22.17, and a second page "5" indicating a test panel of 10 subjects and a mean SPF value of 19.71.[4] Yet, the concluding page 6 of the Suncare Report refers only to the 6-member panel and mean SPF value of 22.17, a clear deviation from the FDA's 10-member panel requirement.

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[4] (See Saltarelli Dec., Ex. 5, at Page 3 (advising Plaintiff's counsel: "In addition, based on our preliminary review of the Suncare Research test report attached to the draft complaint, it appears that, in contrast to the SPF testing conducted by AMA Labs and BioScreen, Suncare's testing was not conducted in accordance with the FDA Final Rule.").) Indeed, Suncare Labs' own testing "Protocol" acknowledges the minimum 10-member panel requirement. (Compl., Ex. A, Doc. 1-3, at page 69 of 81.) Plaintiff offers no explanation for the discrepancy.

Despite Plaintiff having knowledge and copies of all four FDA-compliant tests conducted for Swiss-American and validating UV Aero's stated SPF value of 45, the Complaint, filed December 7, 2015, contains no reference to any of them. His allegation that UV Aero's SPF value is lower than 45 thus completely ignores the four FDA-compliant tests *he indisputably is aware of* that validate the SPF 45 value on UV Aero's label. Worse, his allegations that Swiss-American is intentionally misleading customers about the SPF value of UV Aero are entirely contradicted by the test reports provided to Plaintiff's counsel, in good faith and at his request.

Based on such disingenuous, if not intentionally misleading pleading, Plaintiff seeks certification of a nationwide class and a subclass of individuals who purchased the product in New York during the alleged class period. (Id. ¶¶ 29-33.) Plaintiff asserts 10 claims: (A) on behalf of himself and a similarly situated class of New York residents, for violation of New York's consumer protection and false advertising statutes (first, second, and third claims); (B) on behalf of himself and a nationwide class, for violation of the consumer protection statutes of 41 states in addition to New York (fourth claim); (C) on behalf of himself and a nationwide class, for violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 et seq. (fifth claim); and (D) on behalf of himself and a nationwide class, common-law claims for breach of express warranty under various state statutes (sixth claim), breach of implied warranty of merchantability (seventh claim), breach of implied warranty of fitness for a particular purpose (eighth claim), unjust enrichment (ninth claim), and negligent misrepresentation (tenth claim). (Compl. ¶¶ 43-134.)

Plaintiff seeks injunctive relief directing Swiss-American "to correct its quality control and product labeling practices and to comply with applicable state and federal law," as well as monetary, treble and punitive damages, costs, and attorneys' and expert fees. (Id. at pp. 32-33.)

ARGUMENT

I. Plaintiff's Claims Are Pre-empted By The Federal Food, Drug and Cosmetic Act.

A. The Statutory and Regulatory Framework Applicable to Sunscreen

As Plaintiff acknowledges, (Compl. ¶¶ 8-9), the FDCA and FDA regulations set forth a comprehensive regulatory framework governing SPF value testing and labeling requirements for sunscreen products sold in the United States.

The FDCA "authorizes the FDA to regulate" the "labeling" of OTC drugs, including "sunscreen products" like UV Aero. See Eckler v. Neutrogena Corp., 189 Cal. Rptr. 3d 339, 344 (Cal. Ct. App. 2015). Section 751 of the FDCA, codified at 21 U.S.C. § 379r(a), prohibits any state requirements on OTC labels that are not identical with the federal requirements: "no State . . . may establish or continue in effect any requirement – (1) that relates to the regulation of a drug . . . and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter . . . ." Although the FDCA contains a "savings clause," 21 U.S.C. § 379r(e), it is inapplicable here because it excepts from preemption only state product liability suits, and Plaintiff asserts no such claim. See Eckler, 189 Cal. Rptr. 3d at 345 & n.4.

Section 379r of the FDCA reflects Congress's "express intention generally to preempt state requirements on the labeling of nonprescription drugs such as the sunscreen products at issue" in this case, and stems from its desire to ensure a "national uniform system of regulation" of such products. Id. at 345 (citation omitted).

Sunscreen products "have been the subject of exhaustive federal regulatory action for many years." Id. at 346. Decades of rulemaking culminated, in June 2011, in the FDA's issuance of a "Final Rule" regulating the testing and labeling of sunscreen products: Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed.

Reg. 35620 (June 17, 2011) (the "FDA Final Rule"). Recognizing that the FDA Final Rule governs the viability of his claims, Plaintiff himself attaches a copy of it to his Complaint.

The FDA Final Rule "mandate[s] that sunscreen labels state the SPF value resulting from the detailed testing procedure described in" 21 C.F.R. § 201.327(a)(1) & (i). Eckler, 189 Cal. Rptr. 3d at 348; Gisvold v. Merck & Co., Inc., 62 F. Supp. 3d 1198, 1202 (S.D. Cal. 2014) (same). All sunscreen manufacturers must test SPF values in accordance with the detailed protocol described in the FDA Final Rule, and set forth the result of such testing on the label. Eckler, 189 Cal. Rptr. 3d at 348 (citing 21 C.F.R. § 201.327(a)(1) & (i)).[5]

In sum, the FDA Final Rule "made clear that section 379r requires preemption of suits based on state law (other than product liability actions) that would seek to impose any labeling or advertising requirements not identical to those contained in the Final Rule." Eckler, 189 Cal. Rptr. 3d at 349.[6]

B. The FDCA Expressly Pre-Empts All State Requirements Pertaining to Sunscreen Labeling That are Not Identical to Federal Requirements.

In pre-emption cases, "'the question is whether state law is pre-empted by a federal statute, or in some instances, a federal agency action.'" Gisvold, 62 F. Supp. 3d at 1201 (quoting POM Wonderful LLC v. The Coca-Cola Co., 134 S. Ct. 2228, 2236 (2014)). The FDCA

[5] As required by the FDA, UV Aero is registered in the FDA's National Drug Code Directory (listed under "Elta MD UV Aero" bearing product number 60232-2587). See http://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm.

[6] Indeed, Congress was so intent on ensuring a national system of regulation of sunscreens that, on May 25, 2011, a bill was introduced in the Senate that would have had the FDA's 2007 "proposed" sunscreen regulations take effect 180 days after passage of the bill, unless the FDA issued a "final rule" regarding the "formulation, labeling, and testing requirements" for sunscreen before such effective date. See "Sunscreen Labeling Protection Act of 2011" (S. 1064) (https://www.congress.gov/bill/112th-congress/senate-bill/1064/text) (accessed January 20, 2016). The FDA issued the FDA Final Rule on June 17, 2011.

regulates the labeling of sunscreen products, and its "express pre-emption" provision – Section 379r – is "unambiguous and broad in scope[.]" Gisvold, 62 F. Supp. 3d at 1202.

The FDA Final Rule "*mandate*[*s*] that OTC sunscreen labels state the SPF value resulting from the detailed testing procedure described in" 21 C.F.R. § 201.327(a)(1) & (i), and sets forth the "highly technical standards for the testing and measurement of [SPF values]." Eckler, 189 Cal. Rptr. 3d at 346; Gisvold, 62 F. Supp. 3d at 1202.

Plaintiff's claim is that UV Aero is misbranded because the stated SPF value of 45 is false. See Compl. ¶ 8 (citing 21 U.S.C. § 352(a)); 21 U.S.C. § 352(a) ("A drug or device shall be deemed to be misbranded – (a) If its labeling is false or misleading in any particular."). Such a misbranding claim is expressly pre-empted under Section 379r of the FDCA. Gisvold, 62 F. Supp. 3d at 1202-03 (holding claim that a sunscreen label is false and misleading "expressly pre-empted under 21 U.S.C. § 379r"); Eckler, 189 Cal. Rptr. 3d at 359-60 (same).

Plaintiffs in both Eckler and Gisvold asserted claims of false and misleading sunscreen labeling similar to the one alleged here. And like Plaintiff in this case, the plaintiffs' in Eckler and Gisvold sought relief that was not identical to the federal requirements, which rendered their state law claims pre-empted. For instance, in this case Plaintiff seeks, among other things, injunctive relief "directing [Swiss-American] to correct its quality control and product labeling practices," as well as disgorgement of profits and other monetary relief. (Compl. ¶¶ 40-42 & page 32.) Such claims and requests for relief are pre-empted. Eckler, 189 Cal. Rptr. 3d at 360 ("Eckler seeks disclosure language added to Neutrogena's product label and a corrective advertising campaign. Such an order is expressly preempted by section 379r(a) and (c)."); id. at 360 n.16 (plaintiffs' "claims for purported economic injury are inextricably linked to their labeling and marketing claims" and are pre-empted); Gisvold, 62 F. Supp. 3d at 1201-03 (stating that plaintiff "seeks an order requiring that Merck 'engage in a corrective advertising campaign'"

and holding such a claim to be pre-empted); see Crozier v. Johnson & Johnson Cos., 901 F. Supp. 2d 494, 505 (D.N.J. 2012) (holding that claims relating to the accuracy of an OTC drug's label "are preempted" by FDCA).

Several courts in this Circuit have dismissed claims similar to Plaintiff's on FDCA pre-emption grounds. In Bowling v. Johnson & Johnson, 65 F. Supp. 3d 371, 372, 375-77 (S.D.N.Y. 2014), for example, Judge Scheindlin dismissed claims alleging that a mouthwash label stating that its use could "Restore[] Enamel" was "false and misleading," holding that they were pre-empted in their entirety. Judge Scheindlin noted that the "FDCA does not authorize private causes of action. With respect to the labeling of OTC drugs, the whole point of section 379r is that it is not up to private litigants – or judges – to decide what is 'false or misleading.' It is up to the FDA." Id. at 376-77 (citing Schering-Plough Healthcare Prods. v. Schwarz Pharma., Inc., 586 F.3d 500, 509 (7th Cir. 2009); 21 U.S.C. § 371 (granting the FDA regulatory authority over enforcement of the FDCA)).

Similarly here, Plaintiff's state law claims challenge the accuracy of UV Aero's label with respect to the SPF value and thus "seek to supercede the FDA's regulatory authority." For that reason, therefore, they are expressly pre-empted. Bowling, 65 F. Supp. 3d at 377.

In another virtually identical case, Bimont v. Unilever U.S., Inc., 2015 WL 5256988, at *1, 6-9 (S.D.N.Y. Sept. 9, 2015), Judge Oetken held that state-law claims alleging that a deodorant's label misstated the product's actual net weight were "completely preempted" by the FDCA. The misbranding claim dismissed in Bimont is identical to Plaintiff's claim that the label on UV Aero misstates the product's actual SPF value.

C. Plaintiff's Claims are Also Impliedly Pre-empted.

Plaintiff's claims are also impliedly pre-empted because they are grounded solely upon an alleged violation of the FDCA's labeling requirements. The Supreme Court has held that

Congress intended FDCA requirements to be enforced exclusively by the FDA. Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 352-53 (2001) (common-law claims that "exist solely by virtue of the FDCA" regulations are impliedly pre-empted because FDA regulations represent a "critical element" of the claims); see 21 U.S.C. § 337(a) ("Except as provided in subsection (b) of this section [not relevant here], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Section 337(a) "leaves no doubt that . . . the Federal Government rather than private litigants" is authorized to file suit for alleged violations of the FDCA. Buckman, 531 U.S. at 349 n.4.

In this case, the alleged wrongful conduct is Swiss-American's purported violation of the FDCA's labeling requirements. (See Compl. ¶¶ 8-7 (citing the FDCA's prohibition of "misbranded" sunscreen products and alleging that UV Aero's stated SPF 45 value is false).) Plaintiff alleges no other conduct that purportedly violates the FDCA, or any other federal or state statute or common law. All of his claims derive solely from the alleged violation of 21 U.S.C. § 352's prohibition of false labeling of SPF values. Insofar as Plaintiff is suing "*because* the conduct [allegedly] violates the FDCA," such a claim is also impliedly pre-empted under Buckman. Elkind v. Revlon Consumer Prods. Corp., 2015 WL 2344134, at *9 (E.D.N.Y. May 14, 2015) (emphasis added) (citations omitted).

Elkind involved both mislabeling and deceptive advertising claims regarding cosmetics, which the court assumed for the purpose of its analysis were OTC drugs under the FDCA. Id. at *9. Judge Seybert dismissed the mislabeling claims on express and implied pre-emption grounds because, as in this case, the claims were premised upon a purported violation of the FDCA's branding requirements. Id. at *9 (holding that plaintiffs' mislabeling claims are expressly and impliedly pre-empted where they "arise because Plaintiffs allege that the [product labels] violate the FDCA"; "prosecuting that violation lies squarely within the province of the FDA.").

Although Judge Seybert found that the plaintiff's deceptive advertising claims under Section 350 of the New York General Business Law were not pre-empted, her rationale in doing so actually supports dismissal of Plaintiff's identical claims in this case.

Judge Seybert held that the deceptive advertising claims were "independent" of the FDCA and "would exist even in its absence" because the plaintiff asserted that the statement, "Age Defying with DNA Advantage," was misleading and a determination of whether it was misleading did "not require the Court to interpret, apply, add to, or work through FDCA regulations"; in contrast, 21 U.S.C. § 352 prohibits the sale of an OTC if "'its labeling is false or misleading in any particular,' but goes no further." 2015 WL 2344134, at *8 (internal citation omitted). "So long as courts are not required to perform authoritative interpretation and direct application of FDA regulation," then the fact "that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim." Id. (citation and internal quotation marks omitted).

For these reasons, Plaintiff's deceptive-advertising claims are pre-empted along with his deceptive practices and consumer fraud statutory claims. Every one of his state law claims is grounded upon a purported violation of the FDCA's requirement that SPF values be stated accurately, based upon a test conducted in accordance with the FDA's detailed testing protocol. In sum, Plaintiff alleges that UV Aero's label falsely states an SPF value of 45 when the actual SPF value is lower than 45. To adjudicate his claim will necessitate a determination of whether the stated SPF value of 45 on UV Aero is accurate, which unquestionably would require this Court "to interpret, apply, . . . [and] work through FDCA regulations" setting forth the "highly technical" SPF testing protocol. Any resolution of Plaintiff's claims necessarily would require the Court to perform an "authoritative interpretation and direct application of FDA regulations." For that very reason, all of Plaintiff's consumer protection claims are pre-empted.

Finally, state law consumer protection claims are subject to pre-emption where the FDA has issued regulatory "guidance" regarding the allegedly unlawful practice. Elkind, 2015 WL 2344134, at *8. In fact, the FDA has spent decades considering sunscreen labeling, and issued its Final Rule monograph[7] in June 2011. It has also issued formal compliance "guidance" for sunscreen manufacturers.[8] Because the FDA has issued a final monograph (i.e., the FDA Final Rule) on the subject of SPF labeling – indeed, it has issued regulations setting forth a highly technical and detailed testing protocol from which all advertised SPF values must be derived – courts are not allowed to "intervene" in the same subject matter. Id.

Insofar as Plaintiff's state law claims are grounded solely upon the alleged falsity of the SPF value on the UV Aero label, a purported violation of the FDCA, they are all pre-empted as a matter of law and the Court need not separately consider them. Bowling, 65 F. Supp. 3d at 376-77; Bimont, 2015 WL 5256988, at *1 n.2 ("Because the Court concludes that the Plaintiffs' allegations would be preempted under any applicable state statute, the Court need not specifically evaluate the various state statutes at issue here."); id. at *8 (holding that because "[a]ll of Plaintiffs' well-pleaded factual allegations relate to 'labeling' and 'packaging,'" their "false-advertising claims are dismissed").

Under established pre-emption law, common law tort causes of action "constitute [state] 'requirements' within the meaning of FDCA preemption." Bimont, 2015 WL 5256988, at *9 (dismissing as pre-empted breach of warranty, negligent misrepresentation and unjust-

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[7] "Monograph is the term of art for the regulations that the FDA issues in connection with OTC drugs." Bowling, 65 F. Supp. 3d at 373 n.8 (citation omitted).

[8] (See Saltarelli Dec., Ex. 6 (FDA Guidance for Industry: Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use – Small Entity Compliance Guide (Dec. 2012), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm330694.htm).)

enrichment claims) (citation omitted). Thus, Plaintiff's common law claims for breach of warranty, unjust enrichment, and negligent misrepresentation also fail as a matter of law. Id.

II. Plaintiff Fails to State a Claim Under the Magnuson-Moss Warranty Act.

Plaintiff also fails to state an independent federal claim under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 et seq. ("MMWA"). First, the statement of an SPF value of 45 on UV Aero's label is not a "written warranty" as defined in the MMWA. Under the MMWA, a "written warranty" means "any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time …." Id. § 2301(6)(A).

It is well settled that a written affirmation of fact, e.g., that UV Aero has an SPF value of 45, is not a written warranty under the MMWA unless it promises that it "will meet a specified level of performance over a specified period of time." Id. Even if one could construe the stated SPF value of 45 as a "specified level of performance," which stretches the statutory language beyond recognition, nothing on UV Aero's label promises a specified level of performance "over a specified period of time." At most, then, the SPF 45 statement is a "product description," which is not a written warranty under the MMWA. In re Frito-Lay N. Am., Inc. All Natural Litig., 2013 WL 4647512, at *17 (E.D.N.Y. Aug. 29, 2013) (product label and "description" do not constitute a warranty against a product defect); Bowling, 65 F. Supp. 3d at 378 (same).

The Federal Trade Commission, which administers the MMWA, interprets Section 2301(6)(A) in exactly this way. See 16 C.F.R. § 700.3(a) ("[A] written affirmation of fact or a written promise of a specified level of performance must relate to a specified period of time in

order to be considered a 'written warranty.' A product information disclosure without a specified time period to which the disclosure relates is therefore not a written warranty.").

Plaintiff apparently is aware that the stated SPF value on the UV Aero label does not constitute a "written warranty" under the MMWA. For that reason, he alleges nonsensically that the stated SPF value is an affirmation that UV Aero is "defect free – i.e., not less than SPF 45." (Compl. ¶ 92.) Of course, the stated SPF value has nothing to do with whether UV Aero is free of "defects." Like the "All Natural" label challenged in Frito-Lay, the SPF 45 statement on UV Aero "does not warrant [the] product free from defect" and amounts, at most, to a "product description." 2013 WL 4647512, at *17. Notwithstanding Plaintiff's contrived allegations, the SPF 45 statement on UV Aero does not constitute a written warranty under the MMWA.

Second, it is equally well settled that the MMWA does not create an independent basis for liability, but merely allows recovery under existing state law warranty causes of action. MMWA claims are entirely "derivative" of state law warranty claims, as the federal statute "incorporates state law claims of breach of express and implied warranties." Chiarelli v. Nissan N. Am., Inc., 2015 WL 5686507, at *9 (E.D.N.Y. Sept. 25, 2015). As such, Plaintiff's MMWA claim "falls" with his state law warranty claims, which are entirely pre-empted. Id. Insofar as there are no viable state law causes of action in this case, because each is pre-empted by the FDCA, Plaintiff does not have a viable claim under the MMWA.

Third, even assuming that the SPF value on the UV Aero label constitutes a written warranty under the MMWA (it does not) and that Plaintiff's MMWA claim could survive the pre-emption of his common law warranty claims (it cannot), because the SPF statement on UV Aero's label is expressly governed by the FDCA, the MMWA claim is independently barred under Section 2311(d) of the MMWA, which provides that the MMWA "shall be inapplicable to

any written warranty *the making or content of which is otherwise governed by Federal law*." 15 U.S.C. § 2311(d) (emphasis added).

Fourth, Plaintiff fails even to plead the most rudimentary element of a MMWA claim, i.e., that he paid more than $25 for his bottle of UV Aero. Id. § 2310(d)(3)(A) ("No claim shall be cognizable . . . (A) if the amount in controversy of any individual claim is less than the sum or value of $25[.]"). See Bowling, 65 F. Supp. 3d at 377 n.42 (where individual claim falls below the $25 statutory threshold, the court lacks subject matter jurisdiction under the MMWA).

For all these reasons, Plaintiff fails to state a claim under the MMWA.

III. Plaintiff Fails to State a Claim for Misbranding under 21 U.S.C. § 352(a).

Because Plaintiff's state law claims are all premised upon a purported violation of the FDCA's branding requirements, those claims are expressly and impliedly pre-empted by the FDCA. But although Plaintiff has not expressly asserted an independent misbranding claim under the FDCA,[9] his allegations that Swiss-American violated the FDCA are legally deficient. Like every sunscreen manufacturer, Swiss-American is required by federal law to state an SPF value on its products' labels derived from testing conducted in strict conformity with the testing protocol in the FDA Final Rule. Plaintiff acknowledges this in his Complaint. (Compl. ¶¶ 8-9.)

Although Plaintiff alleges that the SPF value for UV Aero is lower than 45, that assertion appears to be based on a Consumer Reports magazine review and his own testing lab's report. There are no allegations that Consumer Reports derived its SPF value for UV Aero as a result of testing performed in compliance with the FDA's detailed and highly technical protocol. In fact, Plaintiff knows that it did not. (Saltarelli Dec., Ex. 5.)

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[9] Of course, because Plaintiff has no private right of action under the FDCA, he is "foreclosed" from attempting to assert such a claim. Bowling, 65 F. Supp. 3d at 376-77 (rejecting plaintiffs' assertion that if their state law causes of action are pre-empted "their misbranding claim can proceed because it arises independently under" the FDCA).

The second basis alleged by Plaintiff to support his claim that Swiss-American's SPF 45 label for UV Aero is false is Suncare Labs' report. However, a review of that report reveals that it was not performed in compliance with the FDA's testing protocol. (See supra, at pages 3, 6.)

Most significantly, although Plaintiff is aware of them, he has omitted from his Complaint any mention of the four FDA-compliant tests validating the SPF 45 value stated on UV Aero's label. Plaintiff cannot pretend these four test results do not exist simply because they directly contradict his allegations. When the Court considers the test results, Plaintiff fails even to state a claim that Swiss-American has violated the FDCA.

Each of the four tests validating the SPF 45 value on UV Aero's label can, and should be considered by the Court on this motion to dismiss.[10] As the Second Circuit has held, a complaint is deemed to include "'documents that, although not incorporated by reference, are "integral" to the complaint.'" L-7 Designs, Inc. v. Old Navy, LLC, 647 F.3d 419, 422 (2d Cir. 2011) (quoting Sira v. Morton, 380 F.3d 57, 67 (2d Cir. 2004)). A document is deemed incorporated in a complaint when it is "integral" to a plaintiff's "ability to pursue his cause of action." Id. (citation and internal quotation marks omitted); Samuels v. Greenberg, 2015 WL 5657565, at *5 (E.D.N.Y. Sept. 23, 2015) (court may consider "documents that are attached to or referenced in the complaint, documents that the plaintiff relied on in bringing suit and that are either in the plaintiff's possession or that the plaintiff knew of when bringing suit ....") (Irizarry, J.); Silverman v. Unum Grp., 2015 WL 4603345, at *2 (E.D.N.Y. July 30, 2015) (court can consider "documents 'integral' to the complaint, without converting a motion to dismiss into one for summary judgment") (citations omitted) (Irizarry, J.).

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[10] Although Plaintiff's failure to adequately plead a violation of the FDCA provides an additional reason to dismiss Plaintiff's Complaint, all of his claims are subject to pre-emption regardless of whether the Court considers the four test reports. Thus, it is not necessary to consider the four reports to conclude that Plaintiff's claims are pre-empted.

In this case, Swiss-American's four test reports validating the SPF 45 value on the UV Aero label are clearly integral to Plaintiff's ability to pursue his claim of misbranding, since he had notice of the test results and they pertain directly to his claim that the stated SPF value is false. In fact, the test results conclusively negate his assertion. That Plaintiff deliberately chose to omit any reference to the four test reports, for the transparently self-serving reason that they directly contradict his claim, does not alter the fact that the Court properly can, and should, consider them on this Rule 12(b)(6) motion. Cortec Indus., v. SUM Holding LP, 949 F.2d 42, 44 (2d Cir. 1991) ("Plaintiff's failure to include matters of which as pleaders they had notice and which were integral to their claim – *and that they apparently most wanted to avoid* – may not serve as a means of forestalling the district court's decision on [a Rule 12(b)(6)] motion.") (emphasis added); Young v. Suffolk Cnty., 705 F. Supp. 2d 183, 194-95 (E.D.N.Y. 2010) (on a motion to dismiss, the district court can view documents not attached to the complaint "because there was undisputed notice to plaintiffs of their contents and they were integral to plaintiffs' claim") (citation and internal quotation marks omitted); Berman v. SUGO LLC, 580 F. Supp. 2d 191, 201 (S.D.N.Y. 2008) ("Where, as here, the pleader has notice of documents that are integral to its claims, the pleader may not avoid the Court's consideration of such documents simply because they contain material adverse to their claims.") (citing Cortec).

Plaintiff's Complaint specifically refers to Swiss-American's public response to the Consumer Reports review. (Compl. ¶ 14.) That response, entitled "FAQs about EltaMD UV Aero," was published on Swiss-American's website, where it remains accessible today. (Saltarelli Dec., Ex. 2.) Attached to the FAQs document was a copy of the AMA Labs' November 2011 report, which validates the SPF 45 value on the label of UV Aero. (Id.) Insofar as the AMA Labs' report was part of a document expressly referred to in Plaintiff's Complaint, and on which he has relied in asserting his claim, the Court may consider the document even

though it is not attached to the Complaint. L-7 Designs, 647 F.3d at 422; Samuels, 2015 WL 5657565, at *5; Silverman, 2015 WL 4603345, at *2. Although Plaintiff chose to ignore the AMA Labs' November 2011 test report he plainly had notice of and access to, together with all other members of the general public, the Court properly can consider it on this Motion without converting it to one for summary judgment.

Plaintiff also had notice and copies of, but chose to ignore, three other FDA-compliant tests validating the SPF 45 value on UV Aero's label. Prior to filing suit, Plaintiff's counsel contacted Swiss-American and provided an initial draft of his complaint and sought information about Swiss-American's SPF testing. (Saltarelli Dec., Ex. 4.) Swiss-American's counsel then contacted Plaintiff's counsel in response and provided copies of three additional reports, each fully compliant with the FDA testing protocol, which validated an SPF value for UV Aero in excess of 45. (Id., Ex.5.)

Thus, prior to filing suit, Plaintiff and his counsel had notice and copies of four FDA-compliant test reports indicating that the SPF value for UV Aero is stated accurately on the product's label. Despite knowledge of and access to the four reports validating the UV Aero SPF value of 45, Plaintiff does not allege that any of the four tests deviates in any manner from the FDA-mandated testing protocol; indeed, he omits any reference to the four reports. Based on his knowledge of the reports and failure to allege any deviation from the FDA-mandated testing protocol, it is reasonable to assume that Plaintiff has no basis to allege such a deviation. This documentary evidence – which Plaintiff indisputably had in his possession and reviewed prior to filing suit – directly contradicts his assertion that the SPF value of UV Aero is lower than 45 and essentially renders fraudulent his outrageous allegations that Swiss-American is intentionally mislabeling UV Aero and deceiving its customers. (*See* Compl. ¶¶ 17-21, 46-54, 58-65, 68-75, 79-85.)

Although well-pleaded factual allegations in a complaint generally are accepted as true on a Rule 12(b)(6) motion to dismiss, the Court need not accept Plaintiff's scandalous allegations as true because they are directly contradicted by the four test reports of which he had knowledge prior to filing suit. For that reason, the test reports "control," not Plaintiff's spurious allegations. Palm Beach Strategic Income, LP v. Salzman, 2011 WL 1655575, at *8 (E.D.N.Y. May 2, 2011) ("It is well-settled that the Court, on a motion to dismiss, can consider 'documents either in plaintiffs' possession or of which plaintiffs had knowledge and relied on in bringing suit.' Likewise, the Court can consider documents "integral to the preparation of the pleadings.' And '[i]f these documents contradict' the complaint's allegations, 'the documents control' and the Court need not accept the complaint's misstatements as true.") (alteration in original) (citations omitted); Fowlkes v. Rodriguez, 584 F. Supp. 2d 561, 571 (E.D.N.Y. 2008) (same); Russell v. Am. Eagle Airlines, Inc., 2008 WL 2600856, at *3 (E.D.N.Y. July 1, 2008) (same); see Ace Sec. Corp. Home Equity Loan Trust, Series 2007-HE3 ex rel. HSBC Bank USA, N.A. v. DB Structured Prods., Inc., 5 F. Supp. 3d 543, 551 (S.D.N.Y. 2014) (same).

Based on the foregoing, Plaintiff has no credible basis to allege that Swiss-American has violated the FDCA's branding requirements with respect to UV Aero or misled consumers. The Court can, and should consider the four FDA-compliant test reports validating the SPF 45 value on UV Aero's label and disregard Plaintiff's allegations that Swiss-American has intentionally violated the FDCA. Since Plaintiff's allegations of a purported violation of the FDCA underlie each and every one of his claims, all of those claims fall along with his spurious allegations of a violation of the FDCA and, therefore, fail to state any claim upon which relief may be granted.

IV. The Court Should Stay Discovery Pending Its Decision On The Motion To Dismiss

Under Rule 26(c) of the Federal Rules of Civil Procedure, a court may stay discovery pending resolution of a motion to dismiss where there has been a "strong showing" that the

plaintiff's claims lack merit, or where the potentially dispositive motion "appears to have substantial grounds" or "does not appear to be without foundation in law." Williams v. N.Y. St. Off. of Mental Health, 247 F.R.D. 63, 69 (E.D.N.Y. 2007) (citations omitted); Johnson v. N.Y. Univ. Sch. of Educ., 205 F.R.D. 433, 434 (S.D.N.Y. 2007) (citations omitted). Because Swiss-American's motion to dismiss more than meets this standard, discovery should be stayed pending the Court's disposition of Swiss-American's motion to dismiss the Complaint.

Swiss-American's motion clearly sets forth a "substantial" basis – express and implied federal pre-emption – upon which all of Plaintiff's claims should be dismissed; it certainly has a strong "foundation in law." In fact, Swiss-American has made a strong showing that all of Plaintiff's claims lack merit and should be dismissed. Swiss-American has even demonstrated that the factual allegations underlying all of his claims are false and directly contradicted by documentary evidence of which he had notice prior to filing suit. Accordingly, there is no reason why Swiss-American should be burdened with the expense of discovery and related pre-trial proceedings until its motion to dismiss the action, in its entirety and with prejudice, is resolved. Johnson, 205 F.R.D. at 434 ("[B]ecause the adjudication of the pending motion to dismiss may obviate the need for burdensome discovery, defendant's request for a stay of discovery is GRANTED.").

For these reasons, the Court should exercise its discretion and stay discovery pending its disposition of Swiss-American's Rule 12(b)(6) motion.

CONCLUSION

For the reasons set forth above, the Court should grant Swiss-American's motion and dismiss the Complaint, in its entirety and with prejudice, pursuant to Fed. R. Civ. P. 12(b)(6). The Court should also stay discovery pending its disposition of the motion, pursuant to Fed. R. Civ. P. 26(c).

Dated: New York, New York
January 22, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 22, 2016, I served the foregoing on all counsel of record registered with the Court's ECF system, by electronic service via the Court's ECF transmission facilities.

/s/ Joseph J. Saltarelli
Joseph J. Saltarelli